



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) EP 1 066 882 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
10.01.2001 Bulletin 2001/02

(51) Int. Cl.⁷: B01L 3/14

(21) Application number: 00113636.5

(22) Date of filing: 28.06.2000

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE

Designated Extension States:

AL LT LV MK RO SI

(30) Priority: 09.07.1999 US 143215 P
09.09.1999 US 392471

(71) Applicant:

Becton, Dickinson and Company
Franklin Lakes, New Jersey 07417 (US)

(72) Inventors:

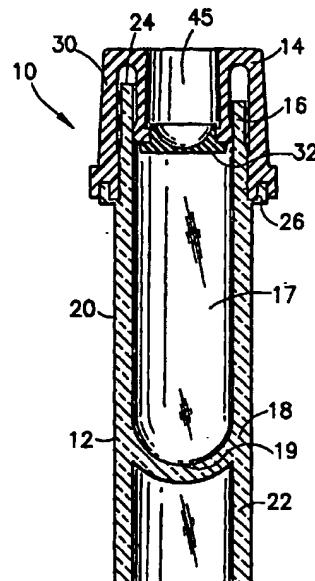
- Rosen, Steven M.
Mountain Lakes, New Jersey 07046 (US)
- Peckham, Allison
Wayne, New Jersey 07470 (US)
- Prais, Alois
Rutherford, New Jersey 07070 (US)

(74) Representative:

von Kreisler, Alek, Dipl.-Chem. et al
Patentanwälte,
von Kreisler-Selting-Werner,
Bahnhofsvorplatz 1 (Deichmannhaus)
50667 Köln (DE)

(54) Specimen collection assembly with cap

(57) The present invention is a collection assembly (10) comprising a container (12), a cap assembly (14) removably and sealably secured to the container (12) whereby access to the interior of the container (12) can be made with a piercing element without removing the cap assembly (14) from the container. The cap assembly includes a cap body (30) and a membrane like septum (32) supported by the cap body (30). The septum (32) provides for a pierceable element to have access to the interior of the container. The membrane is a thermoplastic elastomer and is self-sealing upon removal of the piercing element.



Description**BACKGROUND OF THE INVENTION****1. Field of the Invention**

[0001] The present invention relates to a collection assembly and more particularly to a microcollection container and cap assembly suitable for collecting small quantities of a specimen such as blood from a patient, that provides access to the interior of the container without the need for removing the cap from the assembly and for maintaining a specimen in secure fashion for subsequent testing.

2. Description of Related Art

[0002] Analytical instrumentation has made it possible to carry out a variety of hemological diagnostic procedures on very small quantities of blood. The blood may be collected from a small puncture placed in a patient's finger or ear lobe. The blood is collected in a microcollection container. Once the small quantities of blood are collected, the container is sealably covered by a cap.

[0003] In order for a laboratory technician to conduct tests on the blood sample which is collected in the container, the cap must be removed from the container so as to provide access to the blood sample. In the alternative, the entire contents of the container may be transferred from the container to an instrument compatible sample holder in order for laboratory analysis to take place.

[0004] Therefore, there is a need for a microcollection container that is (i) compatible with instruments for laboratory analysis whereby the specimen does not have to be transferred out of the container for analysis to be conducted; (ii) provides a resealable portion for easy access into the container by a needle or probe that also prevents specimen leakage out of the container; (iii) maintains a specimen in secure fashion; and (iv) prevents contamination to the specimen and to the user.

SUMMARY OF THE INVENTION

[0005] The present invention is a collection assembly comprising a container and a cap.

[0006] The container includes an open end, a closed end and a cylindrical wall therebetween which preferably comprises the interior of the container for accommodating the specimen.

[0007] Desirably, the cap comprises a cap body removably sealably secured to the open end of the container. The cap body supports a membrane for providing resealable access to the interior of the container. The membrane is formed of a material which is capable of being pierced and resealed on a repetitive basis with a needle or instrument probe. Most preferably, the mem-

brane is formed of a thermoplastic elastomer. Such thermoplastic elastomers include isoprene propylene, such as MONOPRENE (a trademark of QST, Inc.) sold by QST, Inc., St. Albans, Vermont.

5 [0008] Preferably, the membrane is disc-shaped having a concave surface facing away from the container interior which assists in resealing of the membrane. The thermoplastic elastomer allows for the resealing of the pierced membrane in a manner which

10 prevents specimen leakage therethrough even when the collection assembly is held in an inverted position.

[0009] Preferably, the cap body includes a top portion, a bottom portion, a cylindrical sidewall extending from the top portion to the bottom portion having an inner surface and an outer surface, an access passageway at the top portion and a membrane supported across the passageway.

[0010] The cap body may further include a depending annular skirt extending into the interior of the container from the top portion and defining an annular region with the cylindrical sidewall. The open end of the container is accommodated within the annular region. The depending skirt includes an access passageway, with the membrane being supported across the passageway.

20 [0011] Preferably, the membrane and the cap body may be co-injection molded or insert molded.

[0012] An advantage of the present invention is that it facilitates direct access to a sample for diagnostic instrumentation systems and enables microcollection tube compatibility with diagnostic instrumentation by providing features such as pierceability and self-resealing of the cap.

25 [0013] Still another advantage of the present invention is that the self-sealing pierceable cap permits mixing of the specimen in the container without transferring the specimen to another container and providing for direct access to the specimen via the self-sealing pierceable cap by diagnostic instrumentation.

30 [0014] Most notably, is that the present invention permits a specimen to be accessed through the top of the cap without removing the cap from the container, thereby providing minimal exposure of the specimen to the user.

35 [0015] In addition, the present invention permits the assembly to be directly used on instrumentation similar to that used for evacuated collection assemblies.

[0016] Advantages of the membrane of the present invention include that: (i) it can be pierced and resealed many times; (ii) it requires less than 2 lb. force for a piercing element to pierce it; and (iii) the concave shape aids in the ability of the membrane to seal properly after the piercing element is removed.

DESCRIPTION OF THE DRAWINGS

[0017]

FIG. 1 is a front plan view of the collection assembly of the present invention.

FIG. 2 is a perspective view of the collection assembly of FIG. 1 illustrating the container, the cap and the membrane.

FIG. 3 is a cross sectional view of the collection assembly of FIG. 1.

FIG. 4 is a side elevational view, partially in section of the collection assembly of FIG. 3.

FIG. 5 illustrates the collection assembly of FIG. 4, with a probe extending thereinto.

DETAILED DESCRIPTION

[0018] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1-3 illustrate the collection assembly 10 of the present invention.

[0019] Collection assembly 10 includes a container 12 and a cap assembly 14. Cap assembly 14 may be removably secured to the container.

[0020] Container 12 is an elongate member having an open upper end 16, a lower end 18 including a rounded closed bottom 19 and a cylindrical wall 20 extending therebetween. The cylindrical wall 20 defines an interior 17 internally thereof for accommodating a specimen such as a blood specimen. The cylindrical wall 20 extends beyond the rounded closed bottom 19 to form an annular extension 22 which permits container 12 to stand upright on a flat surface.

[0021] As shown in FIG. 2, open upper end 16 of container 12 includes a beveled distal rim 24 for facilitating collection of a blood sample. The upper end 16 of tube 12 further includes a radially outwardly extending cap seating flange 26 which provides for the removable sealable attachment of cap assembly 14 on upper end 16 of container 12. Once a specimen, such as blood is collected in interior 17 of the container, the container may be sealingly closed by cap assembly 14.

[0022] Referring to FIG. 4, cap assembly 14 includes a cap body 30 and a sealable septum 32 supported by cap body 30. Cap body 30 is preferably an integrally formed molded plastic member generally in the shape of an inverted cup. The cap includes a flat upper surface 34, an opposed open lower surface 36 and a cylindrical sidewall 38 extending therebetween. The distal end of cylindrical sidewall 38 adjacent open lower surface 36 defines an annular groove 39 for accommodating cap seating flange 26 of the container. Cylindrical side wall 38 includes a plurality of inwardly

directed protrusions 40 which engage an exterior surface of cylindrical wall 20 of the container about open upper end 16 to provide sealed engagement between cap body 30 and container 12.

[0023] Cap body 30 further includes a centrally located depending annular skirt 42 extending from flat upper surface 34. Annular skirt 42 and cylindrical side wall 38 form an open ended annular recess 43 therebetween for accommodating upper end 16 of container 12.

[0024] Annular skirt 42 includes an open upper extent 44, an opposed open lower extent 46 extending into interior 17 of the container and a central passageway 45 therebetween which provides access through cap body 30 and into interior 17 of container 12. Lower extent 46 of annular skirt 42 includes an outwardly directed annular rib 48 which is engageable with an inner surface of cylindrical wall 20 adjacent open upper end 16 of container 12 to facilitate sealing of cap body 30 with container 12.

[0025] Cap body 30 further supports septum 32 at the lower extent 46 of annular skirt 42. Septum 32 is a disc-like membrane formed of a thermoplastic elastomer. As shown in FIG. 4, septum 32 includes a planar portion 50 and an upwardly extending annular ridge 52. Annular ridge 52 has a diameter which allows it to be force fitted within open lower extent 46 of annular skirt 42 and retained in sealed engagement. Planar portion 50 of septum 32 faces towards the interior of container 12. Annular ridge 52 defines a concave surface 53 in opposition to planar portion 50. Septum 32 defines a centrally located portion 54 having a thickness of about .028 inches. Portion 54 allows the septum to be easily pierced by a cannula or probe used to extract a liquid sample from interior 17 of container 12 with about 2 pounds of force.

[0026] In use, a liquid sample is collected in container 12 and then cap assembly 14 is sealably secured to the open upper end of the container.

[0027] As shown in FIG. 5, a sample probe or cannula 60 may be inserted into container 12 by inserting cannula 60 through passageway 45 of cap body 30. The distal tip 62 of cannula 60 may then pierce through septum 32 at portion 54. Since the material of septum 32 is a soft thermoplastic elastomer, septum 32 is easily pierced by low insertion forces. Therefore, for a relatively wide instrument probe having a diameter of about .0625 inches, portion 54 of septum 32 may be pierced by a force of less than 2 pounds.

[0028] Insertion of cannula 60 continues until it reaches the sample in interior 17 of container 12 and then collects a portion of the sample. Cannula 60 is then removed by withdrawing it back through passageway 45. Upon withdrawing cannula 60 from septum 32, the thermoplastic elastomer septum self-seals. In addition, concave surface 53 facing in opposition thereto helps reseal a hole placed in septum 32 by cannula 60. The septum shape defines a concave surface in the direction of cannula withdrawal. The compressive forces exerted by such a shape assist in resealing of any hole.

placed in septum 32 as cannula 60 is withdrawn from the container. Thus, the particular configuration of septum 32 as well as the material from which it is formed permits the septum to reseal after multiple puncture sites have been placed therein. The liquid sample in container 12 can therefore be repeatedly sampled with the septum self-sealing upon each sample extraction.

[0028] The collection assembly of the invention may be made of a molded thermoplastic material so that the specimen collected may be readily viewed. Representative materials include, for example, polyethylene, polypropylene and polyvinyl chloride. The collection container may incorporate a hydrophilic material or a silicon, or a texture may be applied to the internal surface thereof for enhancing the flow and mixing of blood introduced into the container.

[0029] Although it is within the purview of the invention to provide caps which are colored to defined specific forms of fluid collection containers containing materials for one reason or another or for defining the kind of examination to be conducted on the specimen collected, transparent caps may be provided. Also, it should be noted that the dimensions of the container are such as to provide space for labeling which may be important for identifying the collected specimens.

Claims

1. A specimen collection assembly comprising:

an elongate specimen collection tube having an open end, a closed end and a cylindrical wall therebetween defining a tube interior for accommodating said specimen; and;
 a cap assembly having a cap body removably sealably secured to said open end of said tube, said cap body supporting a membrane for providing therethrough pierceable probe access to said tube interior, said membrane being formed of a thermoplastic elastomer and being self-sealing upon probe removal.

2. The specimen collection assembly of Claim 1, wherein said membrane is disc-shaped having a flat surface, an opposed concave surface facing away from said tube interior and is sealingly supported by said cap body.

3. The specimen collection assembly of Claim 2, wherein said cap body comprises an upper surface, an opposed lower surface and a cylindrical side wall therebetween, said cylindrical side wall being sealably engageable with said open upper end of said tube.

4. The specimen collection assembly of Claim 3, wherein said cap body further comprises a depending annular skirt extending from said upper surface

5 of said cap body, said cylindrical side wall and said annular skirt defining an annular region therebetween for accommodating said open end of said tube, said annular skirt defining an access passageway through said cap body and said membrane being supported within said access passageway.

10 5. The specimen collection assembly of Claim 4, wherein said annular skirt comprises an elongate cylindrical skirt wall having an upper end and a lower end with said passageway being defined therebetween, said lower end of said skirt wall extending into said tube interior and said membrane being sealingly supported across said lower end of said skirt wall.

15 6. A cap assembly for sealably covering an open ended specimen collection container comprising:
 20 a cap body being formed of rigid material for removable securement over said open end of said container; and
 a pierceable septum supported by said cap body for providing probe pierceable access to said container through said cap, said pierceable septum being formed of a thermoplastic elastomeric membrane capable of self-sealing upon probe removal.

25 7. The cap assembly of Claim 6, wherein said cap body defines a probe passageway therethrough, said septum is supported across said passageway and is a disc-like member having one concave surface for facilitating said self sealing.

30 8. The cap assembly of Claim 6, wherein said cap body comprises an upper surface, an opposed lower surface and a cylindrical sidewall therebetween.

35 9. The cap assembly of Claim 8, wherein said cap body further comprises a depending annular skirt extending from said upper surface of said cap body, said cylindrical sidewall and said annular skirt defining an annular region therebetween, and said annular skirt defining an access passageway through said cap body and said membrane being supported within said access passageway.

40 10. The cap assembly of Claim 9, wherein said annular skirt comprises an elongate cylindrical skirt wall having an upper end and a lower end with said passageway being defined therebetween, and said membrane being sealingly supported across said lower end of said skirt wall.

45 55

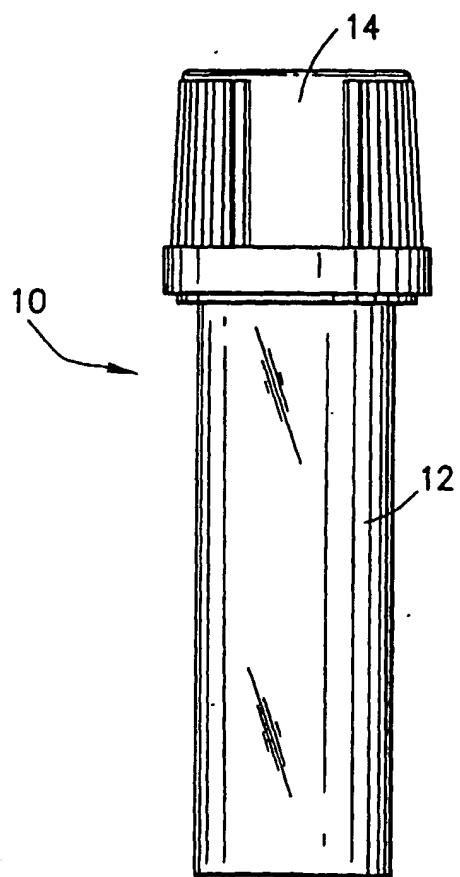


FIG.1

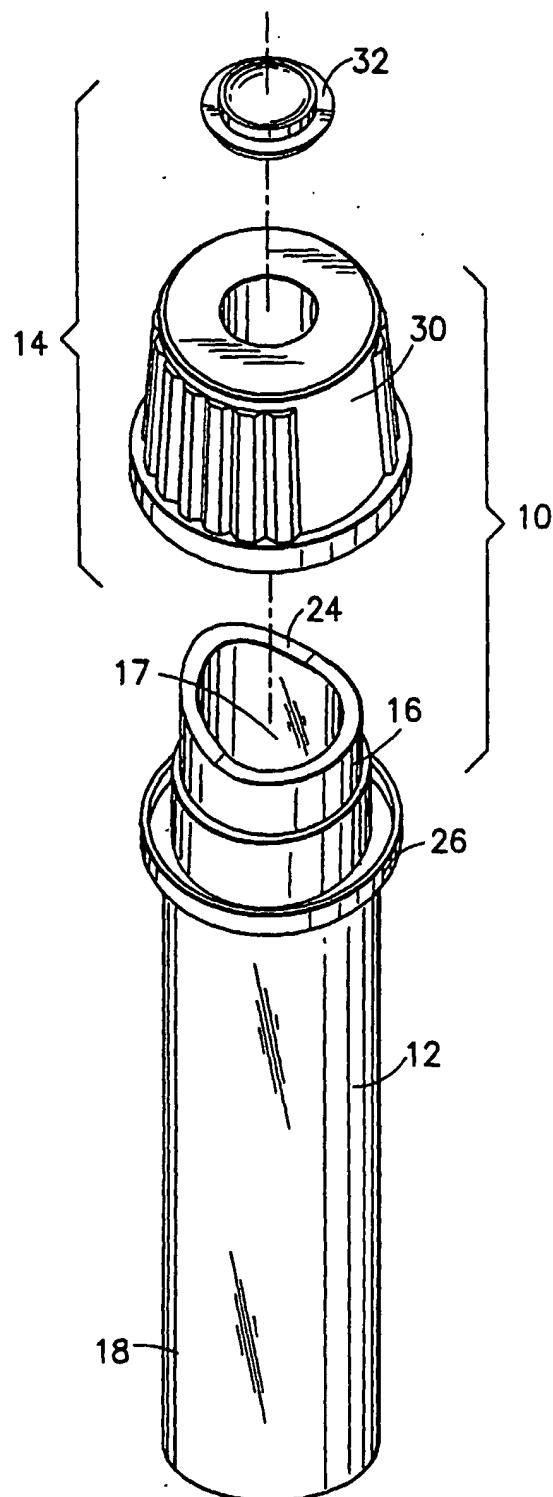


FIG.2

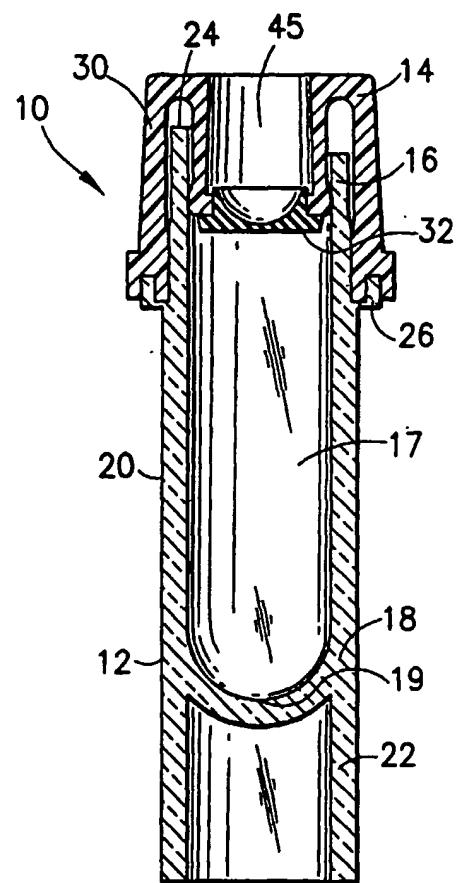


FIG.3

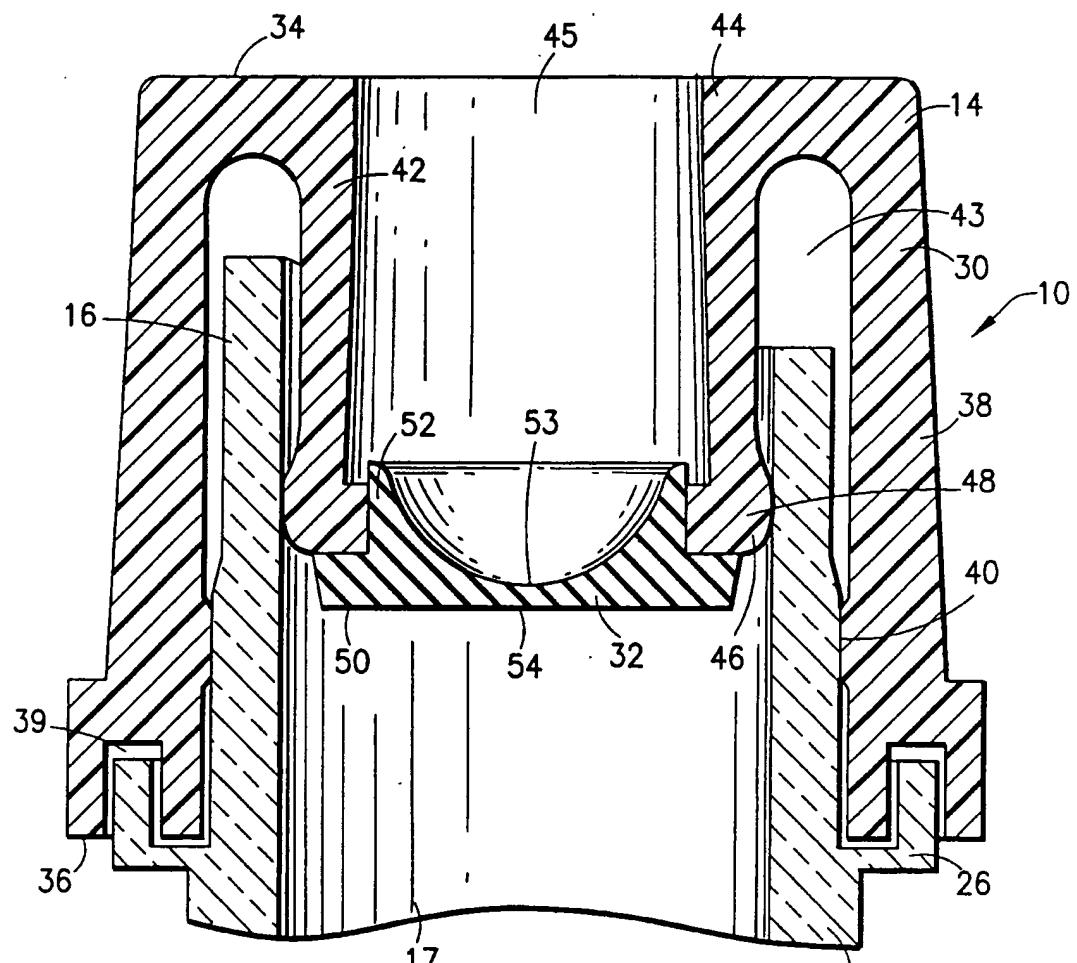


FIG.4

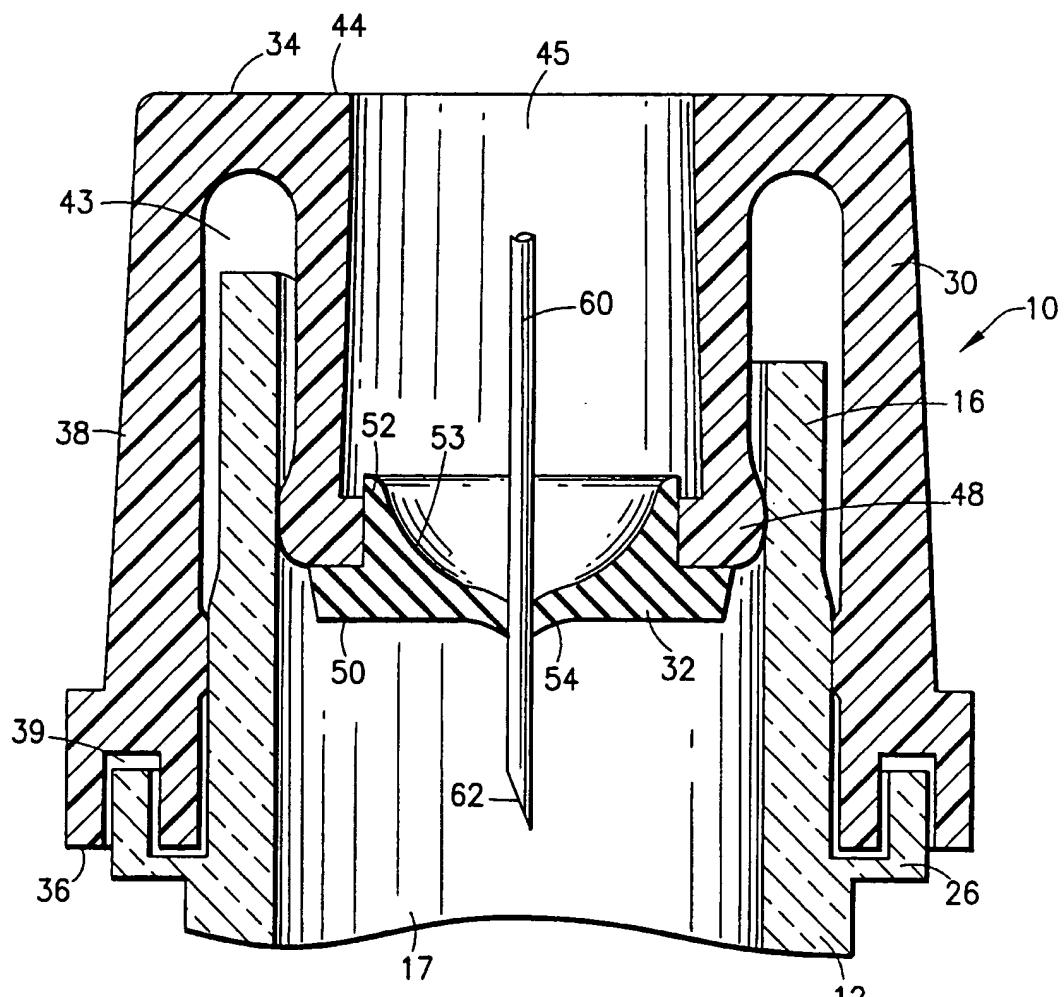


FIG.5



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 00 11 3636

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 738 233 A (BURNS JAMES A) 14 April 1998 (1998-04-14) * column 2, line 62 - column 6, line 54; figures 1-12 *	1-10	B01L3/14
Y	US 4 204 606 A (MICHELI ANTOINE) 27 May 1980 (1980-05-27) * column 1, line 20 - column 1, line 24 * * column 3 - column 5; figure 3 *	1-8	
Y	US 5 247 015 A (BAYAN GHAWAMEDIN) 21 September 1993 (1993-09-21) * column 1, line 20 - column 1, line 50 * * column 2 - column 3 *	1-8	
A	EP 0 445 707 A (GREINER & SOEHNE C A) 11 September 1991 (1991-09-11) * column 4, line 50 - column 6, line 51; figure 1 *	1-10	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)			
B01L			
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	5 December 2001	Runser, C	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 00 11 3636

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

05-12-2001

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5738233	A	14-04-1998	US	5494170 A	27-02-1996
			US	5632396 A	27-05-1997
			US	5699923 A	23-12-1997
			US	5779074 A	14-07-1998
			CA	2121564 A1	07-11-1994
			DE	69403859 D1	24-07-1997
			DE	69403859 T2	13-11-1997
			EP	0623523 A1	09-11-1994
			ES	2105516 T3	16-10-1997
			JP	2608682 B2	07-05-1997
			JP	7051253 A	28-02-1995
US 4204606	A	27-05-1980	CH	603168 A5	15-08-1978
			DE	2611821 A1	30-09-1976
			FR	2304539 A1	15-10-1976
			GB	1545292 A	10-05-1979
			SE	420261 B	28-09-1981
			SE	7603300 A	22-09-1976
			SE	438957 B	28-05-1985
			US	4066067 A	03-01-1978
US 5247015	A	21-09-1993	US	4975308 A	04-12-1990
			CA	2006580 A1	22-06-1990
EP 0445707	A	11-09-1991	AT	401341 B	26-08-1996
			AT	57490 A	15-01-1996
			AT	126097 T	15-08-1995
			AU	646241 B2	17-02-1994
			AU	7267691 A	12-09-1991
			DE	4103459 A1	12-09-1991
			DE	59106176 D1	14-09-1995
			DK	445707 T3	11-12-1995
			EP	0445707 A2	11-09-1991
			ES	2077702 T3	01-12-1995
			GR	3017905 T3	31-01-1996
			HK	30697 A	21-03-1997
			JP	3064444 B2	12-07-2000
			JP	4215961 A	06-08-1992
			RU	2037456 C1	19-06-1995
			US	5294011 A	15-03-1994

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.